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(54) Title: FACILITATING DRAINAGE

(57) Abstract: A prostatic stent comprises a body member and a retaining member. The body member includes a distal terminating end, a proximal end portion, and a lumen extending within the body member to allow fluid drainage through the body member. The body member is sized for placement substantially within the prostatic section of the urethra, with the distal terminating end located proximal of an external sphincter to allow normal operation of the external sphincter. The retaining member extends from the proximal end portion of the body_member. The retaining member is collapsible into a first state to allow passage of the prostatic stent into the urethra, and the retaining member is expandable into a second state when located in a bladder to hold the body member in place substantially within the prostatic section of the urethra.

Summary of the Invention

The invention involves providing drainage of fluid from the bladder of a patient. Systems and methods of the invention typically are used after the patient has undergone prostate treatment such as thermal therapy. Systems and methods according to the invention involve converting in situ a urinary drainage catheter into an indwelling device. The device maintains the prostatic section of the urethra open and able to pass fluid while also allowing normal operation of the patient's external sphincter such that the patient has full and normal control over the retention and discharge of urine from the bladder even with the device in place within the prostatic section of the urethra.

In general, in one aspect, the invention relates to a prostatic stent. The prostatic stent comprises a body member and a retaining member. The body member includes a distal terminating end, a proximal end portion, and a lumen extending within the body member to allow fluid to drain through the body member. The directional terms proximal and distal require a point of reference. In this application, the point of reference in determining direction is in the perspective of the patient. Therefore, the term proximal will always refer to a direction that points into the patient's body, whereas distal will always refer to a direction that points out of the patient's body. The body member is sized for placement substantially within the prostatic section of the urethra. The distal terminating end is positioned proximal of an external sphincter so as to allow normal operation of the external sphincter. The retaining member extends from the proximal end portion of the body member. The retaining member is collapsible into a first state to allow the passage of the prostatic stent into the urethra in the first instance. The retaining member also is expandable into a second state when located in the bladder to hold the body member in place substantially within the prostatic section of the urethra.

Embodiments of this aspect of the invention can include the following features. The retaining member of the prostatic stent can be tapered to provide comfort to the patient during insertion of the stent into the patient's urethra. The retaining member also can comprise two or more retaining arms, and the retaining arms can be biased in the second state. Prior to and during insertion of the prostatic stent into the patient's urethra, the retaining member is in the first state. The retaining member returns to substantially the second state once in the patient's bladder and thereby acts as an anchor to keep the body member of the prostatic stent substantially within the prostatic section of the urethra. The body member of the prostatic stent can include one or more side openings to allow fluid to drain from the prostatic section of the urethra into the lumen. To

at least two retaining arms biased in an expanded state. The retaining arms are collapsible and are collapsed prior and during the insertion of the prostatic stent-catheter into the patient's urethra. The retaining arms in the present embodiment return to the expanded state once located in the patient's bladder and thereby act as an anchor to prevent stent migration. The contraction and the expansion of the retaining arms can be controlled through a pushing device while the prostatic stent-catheter is within the patient's body. The stent portion of the prostatic stent-catheter system can further include a body member comprising of a large pore mesh. The large pore mesh can be fabricated from any biocompatible, self-expanding material such as a nickel-titanium based alloy. The body member including the large pore mesh frictionally engages the patient's prostate, whereby anchoring the stent to prevent migration.

In general, in still another aspect, the invention relates to a method of placing a prostatic stent-catheter system within the urethra. The prostatic stent-catheter system, which includes a stent and a connecting segment releasably coupled to one another, is inserted into the urethra of the patient. A medical professional such as a physician advances the prostatic stent-catheter system through the urethra until at least a portion of the stent is positioned substantially within the prostatic section of the urethra. When properly positioned, at least a portion of the stent will reside within the prostatic section of the urethra, while the connecting segment will extend through the external sphincter, through the rest of the urethra, and outside of the patient's body. The physician will know that the prostatic stent-catheter system is properly positioned when urine or other bodily fluid is observed draining through the distal end of the connecting segment. Bodily fluids such as urine and blood draining through the prostatic stent-catheter system are monitored. If the procedure is being done after treatment (e.g., surgery) on the prostate, the medical professional must determine when the patient's prostate has recovered or is recovering sufficiently from the treatment, and then the professional decouples the connecting segment from the stent and withdraws the connecting segment entirely from the patient's body. The stent thus remains within the prostatic section of the urethra to prevent bladder outlet obstruction and to keep the prostatic section of the urethra open and passing fluid(s) from the bladder while allowing normal operation of the patient's external sphincter. Once the prostate has fully recovered and poses no risk of obstructing fluid drainage, the stent can be removed. Removal of the indwelling stent can be accomplished by pulling on a suture attached to the stent. The suture typically is left extending from the urethra outside of the patient's body, or it can be left just

Brief Description of the Drawings

In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

FIG. 1 is a schematic view of a prostatic stent-catheter system according to one embodiment of the present invention.

FIG. 2 is an exploded view of the prostatic stent-catheter system shown in FIG. 1.

FIG. 3 is a schematic view of one embodiment of a prostatic stent.

FIG. 4 is a schematic view of another embodiment of a prostatic stent.

FIG. 5 is a schematic view of another embodiment of a prostatic stent.

FIG. 6 is a schematic view of another embodiment of a prostatic stent.

FIG. 7 is a schematic view of one embodiment of a pushing device of a prostatic stent-catheter system according to the invention.

FIG. 8 is a schematic view of another embodiment of a pushing device.

FIG. 9 is an enlarged view of the proximal end of one embodiment of a pushing device.

FIG. 10 is an enlarged plan view of a prostatic stent.

FIG. 11 is a side view of the prostatic stent shown in FIG. 10.

FIG. 12 is a cross-sectional view of the prostatic stent taken along the lines 8-8 in FIG. 10.

FIG. 13 is a schematic view of both a handle mechanism in a first position and a corresponding collapsed prostatic stent configuration with an engaged pushing device.

FIG. 14 is a schematic view of both a handle mechanism in a second position and a corresponding expanded prostatic stent configuration with an engaged pushing device.

FIG. 15 is a schematic view of both a handle mechanism in a third position and a corresponding expanded prostatic stent configuration with a disengaged pushing device.

FIG. 16 is a plan view of another embodiment of a prostatic stent-catheter system, in an insertion configuration.

FIG. 17 is an enlarged plan view of the prostatic stent shown in FIG. 16.

FIG. 18 is the prostatic stent-catheter system of FIG. 16 in a release configuration.

FIG. 19 is a schematic view of the prostatic stent-catheter system of FIG. 1, showing the prostatic stent-catheter system in an expanded configuration.

Description

The invention generally relates to relieving bladder outlet obstruction. After prostate treatment, a patient can experience urinary retention. The invention generally involves treating urinary retention, especially male urinary retention, while still allowing normal operation of the patient's external sphincter (and thus allowing normal voiding of the bladder) even with a stent located temporarily within the prostatic section of the patient's urethra.

After a medical procedure to treat an obstructed prostate, such as thermal prostate therapy, a patient may experience prostate bleeding while the recently-treated prostate recovers. Another consequence of such medical procedures is bladder outlet obstruction which results from the still-slightly enlarged and recovering prostate. After the procedure, the medical professional (e.g., a physician) that performed the procedure or some other medical professional will monitor the amount of urine and prostate bleeding, and attempt to provide the patient with an open urinary passageway. In order to monitor continuously the bodily fluids from the patient's bladder and prostate, the medical professional(s) attending to the patient need to prevent the patient's external sphincter from closing to allow constant and uninterrupted drainage of those bodily fluids. In general, the attending professional(s) only need(s) to monitor the flow of blood and urine from the patient's urinary system for a few hours. It may, however, take several weeks for the patient's prostate to recover. One of the objects of the present invention is to provide devices, systems, and methods which will maintain an open passageway throughout the patient's entire urinary system such that constant drainage can be realized for some period of time just after treatment of the prostate, and which also can thereafter provide an open urinary passageway from the bladder through the prostatic section of the urethra while simultaneously allowing normal operation of the patient's external sphincter such that the patient has full and normal control over bladder voiding.

Referring to FIGS. 1 and 2, a prostatic stent-catheter system **1** of the invention comprises a prostatic stent **3** and a connecting segment **6**. The prostatic stent **3** includes a body member **5** made of one or more biocompatible materials such as silicone, nylon, polyglycolic acid, or stainless steel, and sized to fit substantially within the prostatic section of the urethra. The body member **5** has a proximal end **7**, a distal terminating end **4**, and a lumen extending from the proximal end **7** to the distal terminating end **4** to allow fluid drainage through the body member **5**. As previously mentioned in this application, the term proximal refers to a direction that points into the patient's body and the term distal refers to a direction that points out of the patient's

connecting segment **6** and the body member **5**. The guide **40** is fastened to the proximal end **28** of the connecting segment **6** such that a portion of the guide **40** is within the lumen of the connecting segment **6** and the remaining portion extends out from the proximal end **28** of the connecting segment **6**. The remaining portion of the guide **40** is then inserted into the lumen of the body member **5** creating a slip-fit seal between the prostatic stent **3** and the connecting segment **6**. Various other couplings are possible, so long as the distal terminating end **4** of the body member **5** and the proximal end **28** of the connecting segment **6** are releasably joined together. For example, in other embodiments, the guide **40** is releasably coupled to the prostatic stent **3** with sutures that can be removed in situ after the prostatic stent **3** is properly positioned.

After a prostatic procedure to treat an obstructed prostate, such as thermal therapy, the patient's prostate typically will still be slightly enlarged and it may bleed. To prevent bladder obstruction and to monitor the amount of urine production and prostate bleeding, a physician can insert the prostatic stent-catheter **1** into a patient's urethra until the proximal tip **2** is located within the bladder and the connecting segment **6** extends through the external sphincter as to allow constant drainage of fluids from the patient's bladder and through the patient's prostate. Once the physician has decided that the patient's bodily fluids no longer need to be monitored, constant fluid drainage from the patient's bladder is no longer necessary. To avoid the potential risk of bladder retention due to the slightly enlarged and recently treated prostate, however, the physician may wish to maintain the prostatic stent **3** within the prostatic section of the urethra until the prostate is completely resolved. The physician, realizing that patient's prostate could take several weeks to resolve and not wishing to inconvenience the patient, can remove the connecting segment **6** from the prostatic stent-catheter system **1** while leaving the prostatic stent **3** in place by simply pulling on the connecting segment **6**.

The embodiment of the prostatic stent-catheter system **1** of FIGS. 1 and 2 further comprises a pushing device **12** and a handle **20**. The pushing device **12** has a proximal end **36** and a distal end **34**. The width of the pushing device **12** is sized to fit within the lumens of the prostatic stent **3** and the connecting segment **6**; while the length of the pushing device **12** is sized so that the proximal end **36** can contact the proximal tip **2** of the prostatic stent **3** while the distal end **34** extends beyond the distal end **30** of the releasably connected connecting segment **6**. Therefore, the physician performing the procedure can use the pushing device **12** to contact the proximal tip **2** of the prostatic stent **3** once the prostatic stent-catheter system **1** is already inserted into the patient's body. The pushing device **12** can be made from any material that is flexible

larger than the body member **5** but essentially equal to the connecting segment **6**. FIG. 12 is a cross sectional view of the prostatic stent **3**. In this drawing a proximal ledge **15** and a distal ledge **17** are noticeable in the internal prostatic stent **3** profile. The proximal ledge **15** is designed to receive the flange **32** of the pushing device **12** (shown in FIG. 9). The proximal ledge **15** provides a contact surface for the flange **32** to push against when the pushing device **12** is proximally extended. The distal ledge **17** is designed to receive the guide **40** (shown in FIG. 2). The distal ledge **17** provides a contact surface for the guide **40** to rest against while the prostatic stent **3** and the connecting segment **6** are coupled together.

As previously discussed, the prostatic stent **3** as illustrated in FIGS. 1 and 2 includes a retaining member **8** with at least two distinct states. The retaining member **8** is biased in the second state. The physician can change the retaining member's **8** configuration to the collapsed or first state by either applying pressure with his or her fingers to the retaining arms **13a – 13b** to extend the proximal tip **2** in the proximal direction and thus collapse the retaining member **8** or by proximally extending the pushing device **12** within the lumen of the prostatic stent-catheter system **1** to extend the proximal tip **2** and thereby collapse the retaining member **8**. In the latter case, the physician can control the process from outside of a patient's body by placing the mechanism **24** into a first position causing the extension of the pushing device **12**. This process is schematically illustrated in FIG. 13. Similarly, the retaining member **8** can be returned to the second state by either removing the pressure on the retaining member **8** or retracting the pushing device **12** within the prostatic stent-catheter system **1**. FIG. 14 shows the expansion of the retaining member **8** as a result of placing the mechanism **24** in a second position. To detach the pushing device **12** from the prostatic stent **3**, the mechanism **24** is placed into a third position, shown in FIG. 15.

Another embodiment of a prostatic stent-catheter system **100** is illustrated in FIG. 16. The prostatic stent-catheter system **100** comprises a prostatic stent **300** and a connecting segment **600**. The prostatic stent **300** includes a large pore mesh design **350**, a proximal end **370**, a distal end **340**, and a lumen extending between the proximal end **370** and the distal end **340**. An enlarged view of the large pore mesh design **350** is illustrated in FIG. 17. The large pore mesh **350** is fabricated from any self-expanding, biocompatible material such as nylon, polyglycolic acid, stainless steel or nickel-titanium based alloys. The large pore mesh **350** is produced by weaving, braiding, or heat bonding strands of the selected self-expanding, biocompatible materials together or by slotting or pattern cutting by laser and/or conventional machining a

natural state. The prostatic stent-catheter system 1 in FIGS. 19-25 further includes at least one suture 42. In another embodiment, the suture 42 can be replaced with any tubular structure that is thin enough to pass through the external sphincter 54 without negatively impacting the operation of the external sphincter 54 such as a long membrane. The suture 42 or tubular structure can be useful when removing the prostatic stent 3 from the prostatic section of the urethra at some point after the prostate has resolved. To attach the suture 42 to the prostatic stent 3 one end of the suture 42 is threaded through the distal terminating end 4 of the prostatic stent 3. The suture 42 is intended to run parallel to the prostatic stent 3 and connecting segment 6 walls along the lumen to reduce the likelihood of catching and holding blood clots. The other end of the suture 42 can be attached or connected to a retaining device 44. The retaining device 44 serves as a recovery means if the prostatic stent 3 proximally migrates. The retaining device 44 is slidably adjustable along the entire length of the suture 42, thereby allowing the physician to be able to position the retaining device 44 either within or external to the meatus 60. In the disclosed embodiment, the retaining device 44 is located external to the meatus 60 to permit erections. The retaining device 44 in FIGS. 19-25 is a bead. Various other embodiments of retaining devices are possible. Some of the other possible embodiments of retaining devices are illustrated in FIGS. 26-28.

Before a physician can insert the prostatic stent-catheter system 1 including a retaining member 8, the retaining member 8 must be collapsed. FIG. 20 shows a prostatic stent-catheter system 1 of a disclosed embodiment in an insertion or collapsed configuration. FIGS. 21-23 illustrate a method of inserting and placing a prostatic stent-catheter system 1. The remaining drawings, FIGS. 24-25 depict the decoupling of the prostatic stent 3 and the connecting segment 6 and the subsequent removal of the connecting segment 6 from a patient's urethra.

FIG. 21 shows an illustration of both the prostatic stent-catheter system 1 in the insertion configuration (i.e., collapsed retaining member), and a male urinary system 70. The male urinary system 70 including a urethra 58, an external sphincter 54, an opening to the external sphincter 56, a prostate 53, a prostatic section of the urethra 52, and a bladder 50. The point of insertion of the prostatic stent-catheter system 1 is the meatus 60.

To position the prostatic stent-catheter system 1 within a patient to relieve bladder outlet obstruction and to monitor a patient's bodily fluid excretions (post thermal prostate therapy, for example), a physician inserts the prostatic stent-catheter system 1 into a patient's urethra 58 through the meatus 60. This procedure is schematically illustrated in FIG 22. The prostatic

Claims

1. A prostatic stent, comprising:

(a) a body member including a distal terminating end, a proximal end portion, and a lumen extending within the body member, the body member sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of an external sphincter; and

(b) a retaining member extending from the proximal end portion of the body member, the retaining member being collapsible and expandable.

2. The device of claim 1 wherein a proximal portion of the retaining member is tapered.

3. The device of claim 1 wherein the retaining member is formed integrally with the body member.

4. The device of claim 1 wherein the retaining member is biased in an expanded state.

5. The device of claim 1 wherein the retaining member comprises at least two arms biased in the expanded state.

6. The device of claim 1 wherein the body member comprises at least one side opening in communication with the lumen.

7. The device of claim 1 wherein the body member includes at least one protrusion to aid retention of the body member substantially within the prostatic section of the urethra.

8. The device of claim 1 wherein the body member comprises a flexible, compliant material capable of maintaining the lumen when located within the urethra.

9. The device of claim 1 further comprising a suture extending from the medical device through the urethra, and terminating externally of the meatus to allow removal of the medical device from the urethra by pulling the suture.

10. A prostatic stent-catheter system for draining fluid from the bladder and through the prostate after prostate treatment, comprising:

(c) to a third position proximally retracts the pushing device resulting in the absence of contact between the pushing device and the proximal end portion of said stent.

15. The pushing device according to claim 13 wherein the insertion end is straight.

16. The pushing device according to claim 13 wherein the insertion end is curved.

17. The prostatic stent-catheter system according to claim 10 wherein the stent further includes a self-expanding, biocompatible material and a large pore mesh design.

18. The prostatic stent-catheter system according to claim 17 further comprising:

(a) a pushing device slidably receivable by the prostatic stent-catheter system, the pushing device including an insertion end and an external end, the insertion end being able to restrain the proximal end portion of the stent, the pushing device sized to allow the insertion end to restrain the proximal end portion of the stent while the external end remains outside the patient's body; and

(b) a handle secured to the distal end of the connecting segment, the handle including at least one opening to allow fluid drainage out of the handle, and a mechanism, the mechanism being attached to the pushing device to allow a physician to control the position of the pushing device within the lumen of the connecting segment and the lumen of the stent whereby moving the mechanism:

(i) to a first position proximally extends the pushing device resulting in the release of the stent, and

(ii) to a second position proximally retracts the pushing device resulting in the absence of the pushing device within the lumen of the stent.

19. A method of placing a prostatic stent-catheter system, comprising the steps of:

(a) providing the prostatic stent-catheter system which comprises:

(i) a stent comprising a body member including a distal terminating end, a proximal end portion, and a lumen extending within the body member, the body member sized for placement substantially within the prostatic section of the urethra with the distal terminating end located proximal of the external sphincter; and

(ii) a connecting segment comprising an elongated body member including a distal end located outside of a patient's body, a proximal end releasably

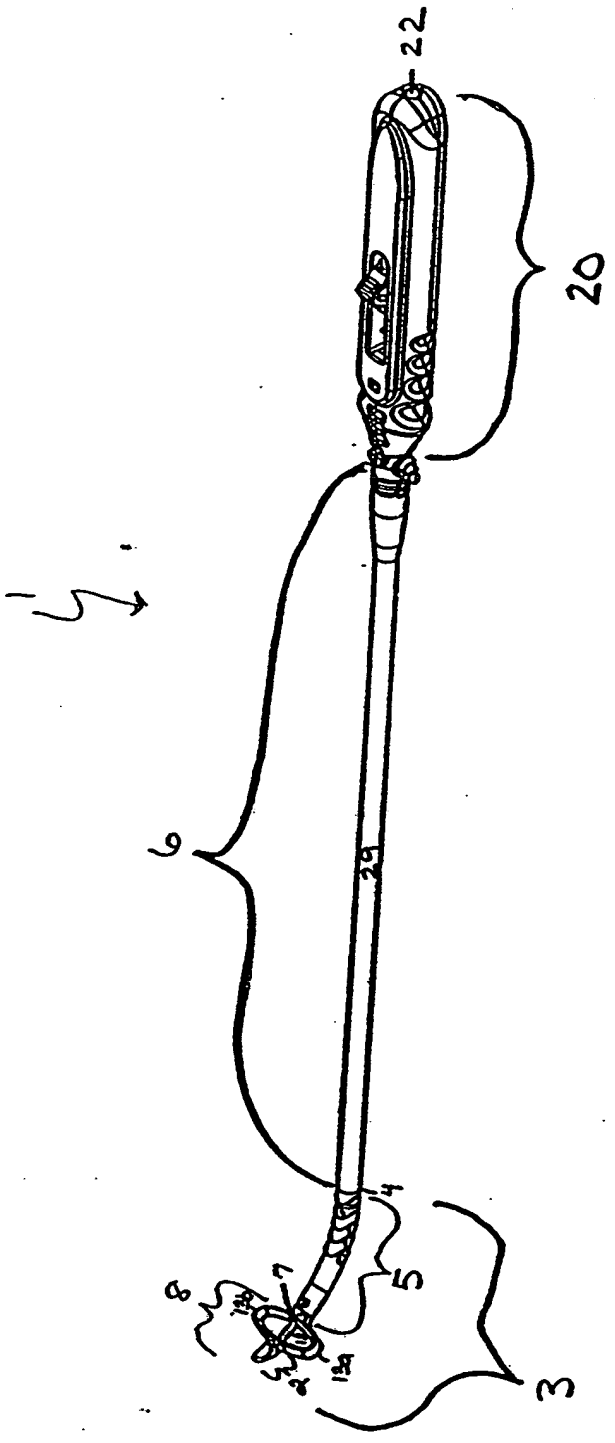


FIG 1

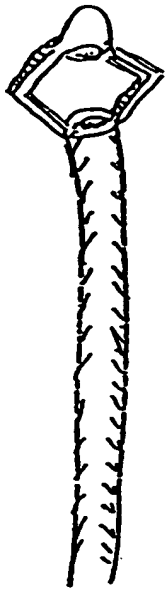


FIG 3

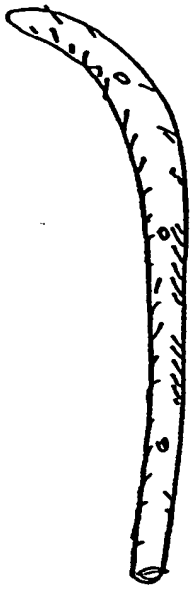


FIG 4

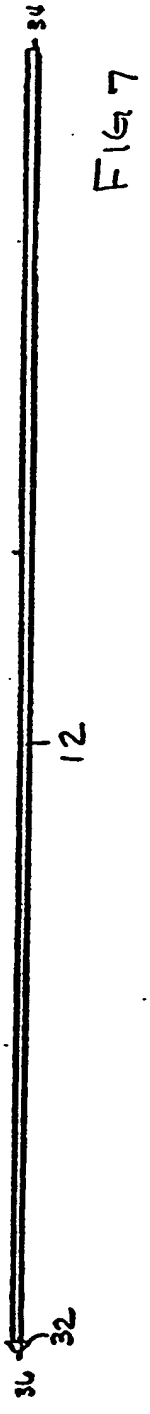


FIG 7

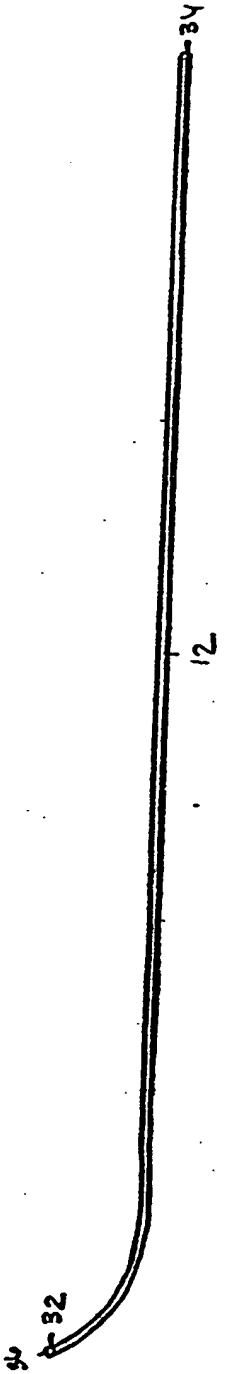


FIG 8

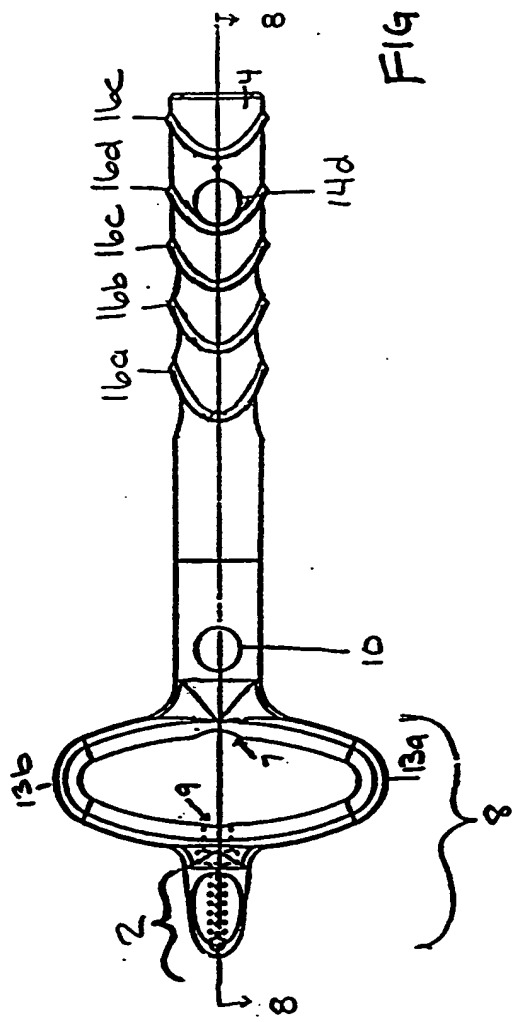
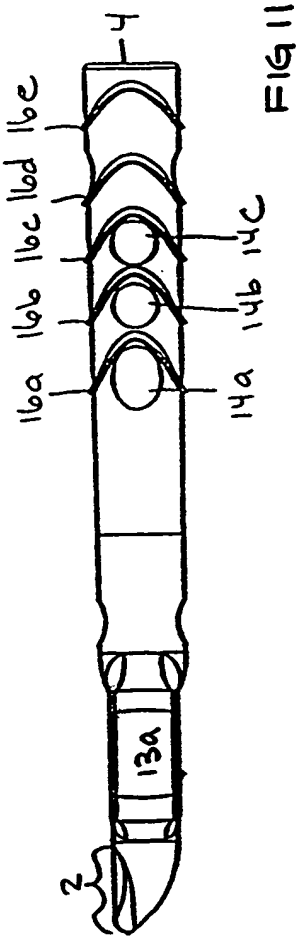

8
4
16a 16b 16c 16d 16e
14d
10
13b
13a
9
7
8
2
8

FIG 10


4
16a 16b 16c 16d 16e
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13a
2

FIG 11

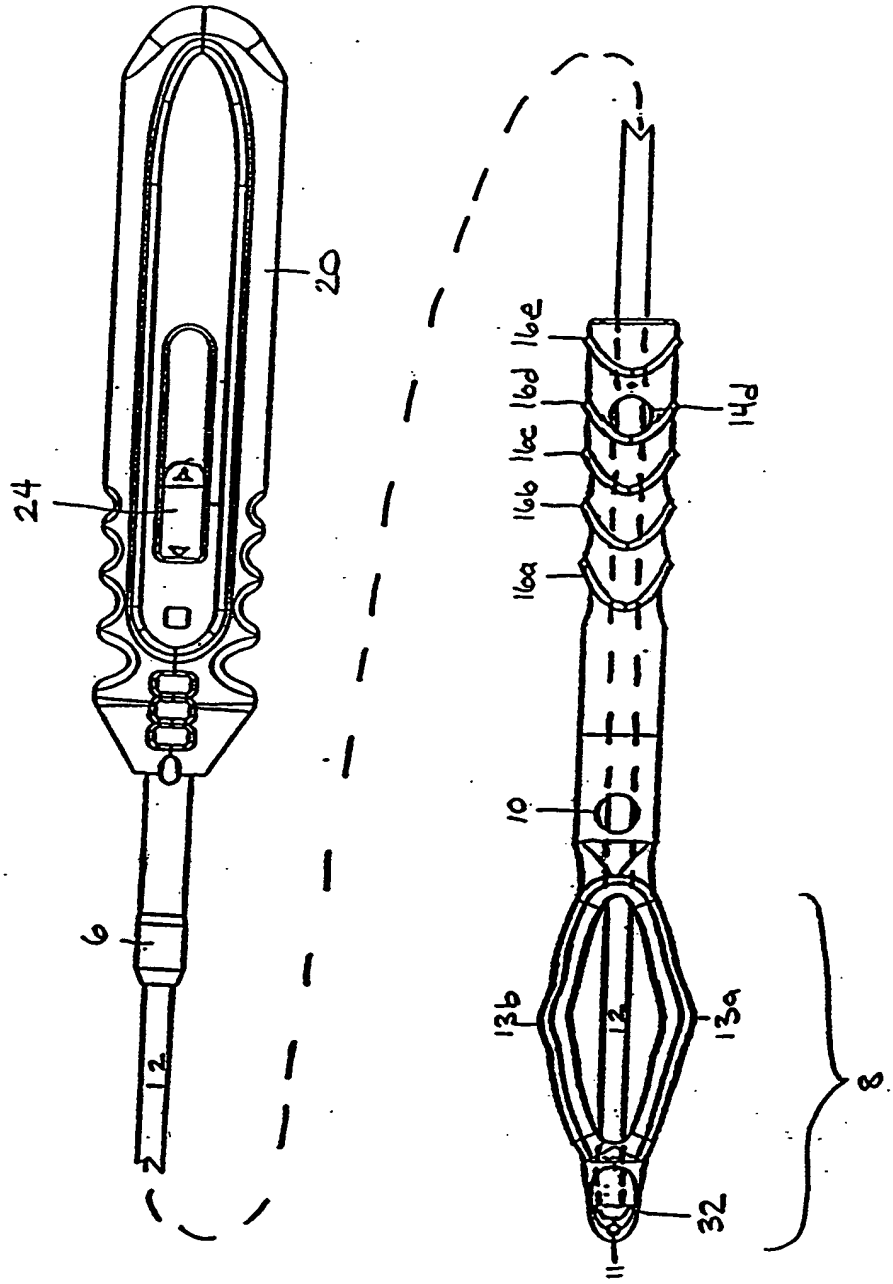

FIG 13

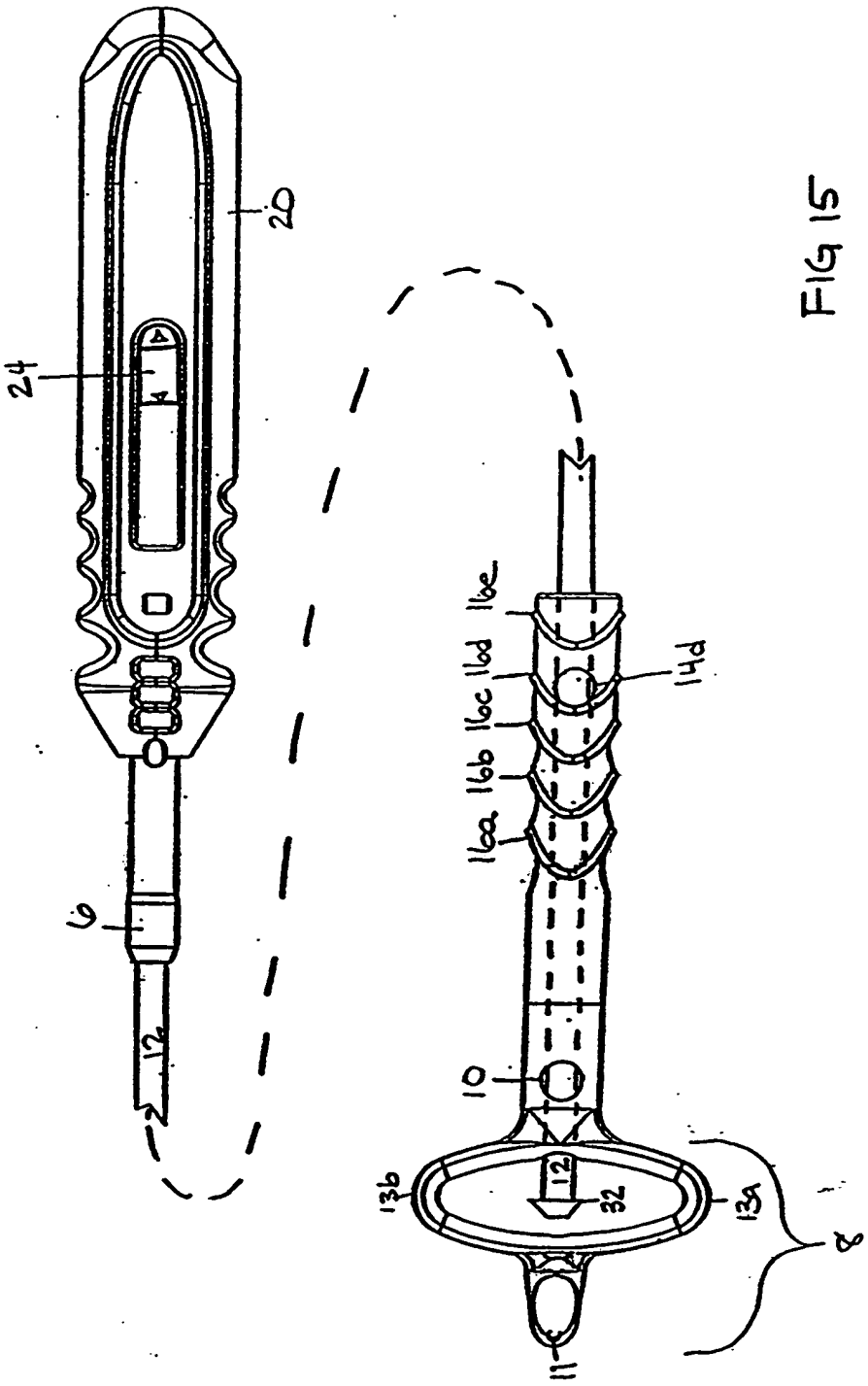

Fig 15

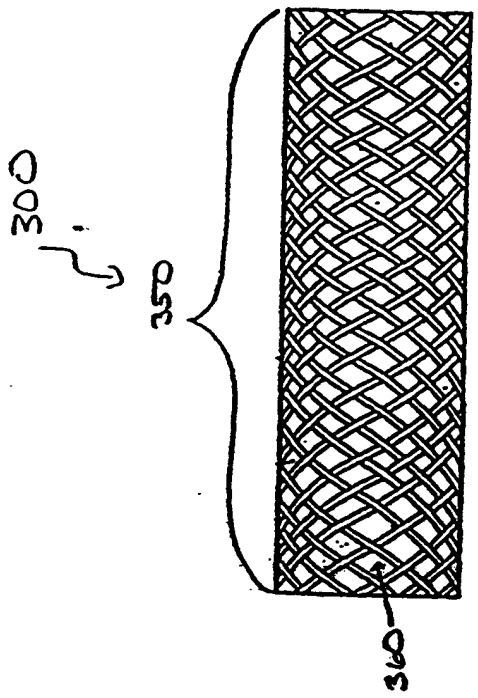

FIG 17

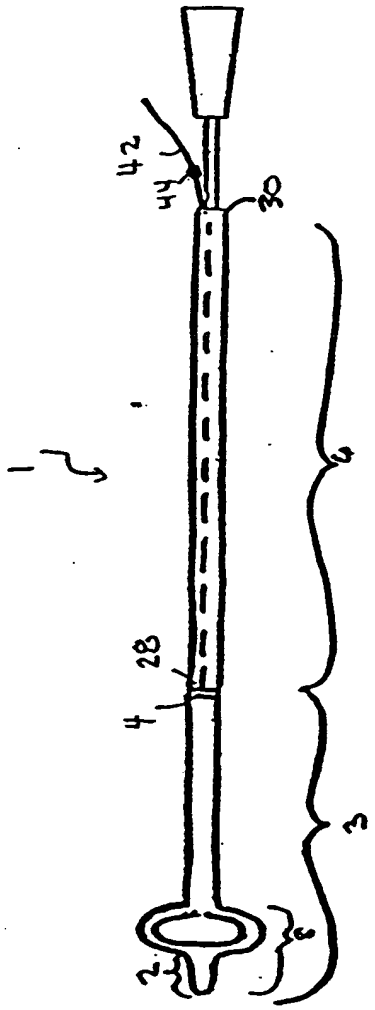

FIG19

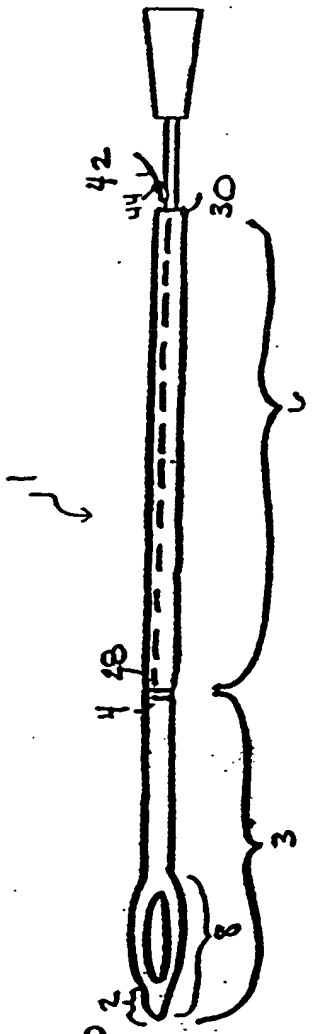

FIG20

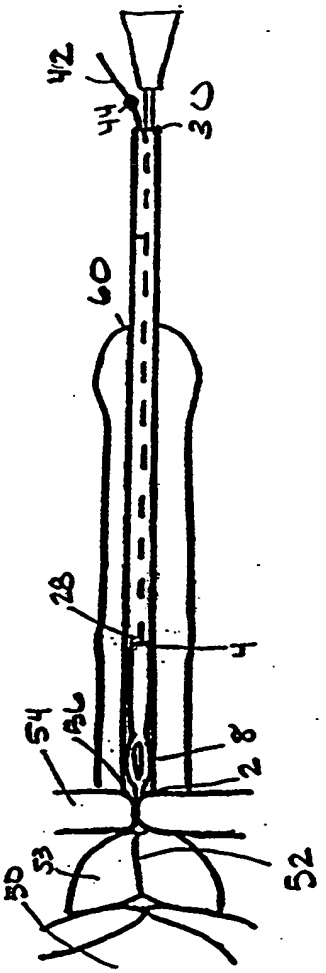

FIG 22

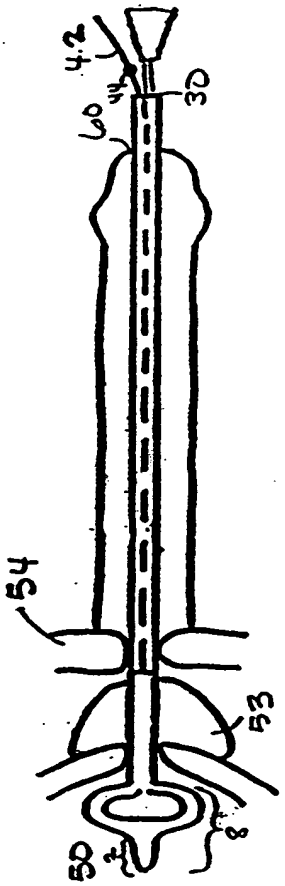

FIG 23

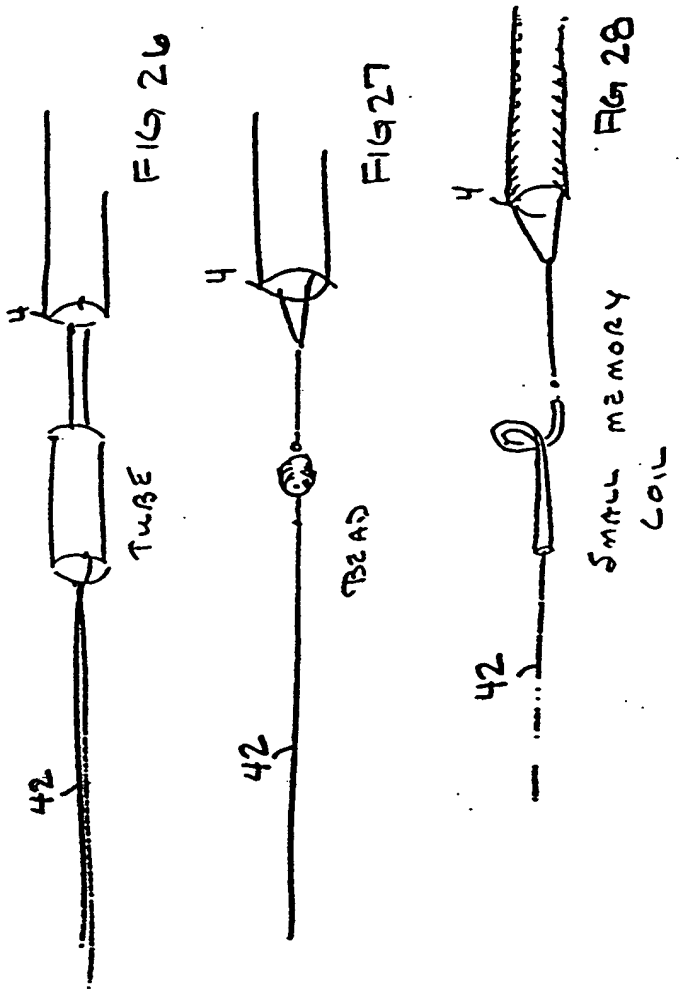
FIG 26
4
TUBE
42
FIG 27
4
BEAD
42
FIG 28
4
SMALL MEMORY COIL
42

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(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

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— *with international search report*

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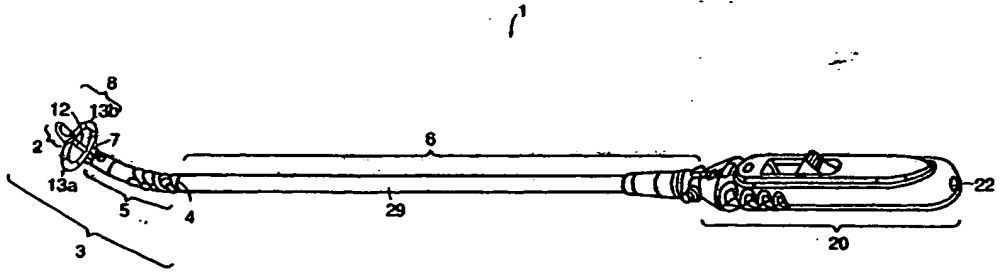
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: PROSTATIC STENT FACILITATING DRAINAGE



(57) Abstract: A prostatic stent (3) comprises a body member (5) and a retaining member. The body member (5) includes a distal terminating end (4), a proximal end portion (7), and a lumen extending within the body member to allow fluid drainage through the body member. The body member (5) is sized for placement substantially within the prostatic section of the urethra, with the distal terminating end (4) located proximal of an external sphincter to allow normal operation of the external sphincter. The retaining member (8) extends from the proximal end portion (7) of the body member (5). The retaining member (8) is collapsible into a first state to allow passage of the prostatic stent (3) into the urethra, and the retaining member (8) is expandable into a second state when located in a bladder to hold the body member (5) in place substantially within the prostatic section of the urethra.

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 01/03001

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 19
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [X] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-8

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

IN RNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 01/03001

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